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STATE OF WISCONSIN
SUPREME COURT

STATE OF WISCONSIN,

Plaintiff-Respondent-Cross-Appellant,

v.

ABBOTT LABORATORIES, ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, AVENTIS BEHRING, LLC f/k/a ZLB BEHRING, LLC, AVENTIS PHARMACEUTICALS, INC., BEN VENUE LABORATORIES, INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM ROXANE, INC., BRISTOL-MYERS SQUIBB CO., DEY, INC., IVAX CORPORATION, IVAX PHARMACEUTICALS, INC., JANSSEN LP f/k/a JANSSEN PHARMACEUTICA PRODUCTS, LP, JOHNSON & JOHNSON, INC., MCNEIL-PPC, INC., MERCK & CO. f/k/a SCHERING-PLOUGH CORPORATION, MERCK SHARP & DOHME CORP. f/k/a MERCK & COMPANY, INC., MYLAN PHARMACEUTICALS, INC., MYLAN, INC. f/k/a MYLAN LABORATORIES, INC., NOVARTIS PHARMACEUTICALS CORP., ORTHO BIOTECH PRODUCTS, LP, ORTHO-MCNEIL PHARMACEUTICAL, INC., PFIZER INC., ROXANE LABORATORIES, INC., SANDOZ, INC. f/k/a GENEVA PHARMACEUTICALS, INC., SICOR, INC. f/k/a GENSIA SICOR PHARMACEUTICALS, INC., SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE, INC., TAP

Appeal No. 2010AP232-AC

PHARMACEUTICAL PRODUCTS, INC.,
TEVA PHARMACEUTICALS USA, INC.,
WARRICK PHARMACEUTICALS
CORPORATION, WATSON PHARMA, INC.
f/k/a SCHEIN PHARMACEUTICALS, INC.
and WATSON PHARMACEUTICALS, INC.

Defendants,

PHARMACIA CORPORATION,

Defendant-Appellant-Cross-
Respondent.

On Appeal from the Circuit Court for Dane County
Case No. 04-CV-1709
The Honorable Richard G. Niess Presiding

THE NON-PHARMACIA BRAND DEFENDANTS' *AMICUS CURIAE* BRIEF AND APPENDIX

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BACKGROUND AND SUMMARY OF ARGUMENT

This appeal involves a series of legislative decisions Wisconsin made when deciding how much to reimburse pharmacists for drugs they dispensed to Medicaid patients. For brand-name drugs, Wisconsin consistently decided to reimburse pharmacists participating in the state's Medicaid program by using a formula based on a drug's Average Wholesale Price ("AWP") as published by third-party pricing compendia.

The term AWP has been used in the context of Medicaid reimbursement for nearly 40 years. For brand name drugs, AWPs have always represented a formulaic markup, typically either 20 or 25 percent, over the drug's wholesale acquisition cost (WAC), which is the invoice price manufacturers charge to wholesalers. *See AstraZeneca LP v. Alabama,* 41 So. 3d 15, 24 (Ala. 2009) ("AWP was calculated by adding 20% or 25% to the reported WAC and thus bore a consistent formulaic relationship to WAC" (internal quotation marks and citations omitted)); R.437 (Tr. 37:8-11), Br.Ap. 23 (State's expert testifying there is a "standard relationship" between a brand-name drug's WAC and the published AWP). As a result, the numbers published as AWPs have a

predictable, mathematical relationship to the marketplace prices for brand drugs.

This predictable relationship has for years led many state Medicaid agencies and private insurers to use AWPs as a starting point to determine the amount pharmacists will be reimbursed for brand drugs. To get from AWP to a desired reimbursement amount, state Medicaid agencies apply a percentage reduction to AWP. They do this because state Medicaid agencies long have known that AWP is not a literal average of wholesale prices.

Wisconsin is no different. It has reimbursed pharmacists who dispense brand-name drugs to Medicaid patients at a discount from AWP for more than two decades. It has set the discount from AWP based on negotiations with pharmacists and its own assessment of what is needed to maintain pharmacist participation in Medicaid. In 1990, Wisconsin changed its reimbursement formula for brand drugs from 100% of AWP to AWP minus 10%. R.135 (Ex. 1 at Tr. 392:18-394:21), Br.Ap. 4. In 2001, Wisconsin changed the reimbursement formula to AWP minus 11.25%. R.135 (Ex. 69:5), Br.Ap. 16. In 2003, it changed the formula to AWP minus 12%, and in 2004, it changed it again to AWP

minus 13%. R.135 (Ex. 1 at Tr. 435:20-436:13), Br.Ap. 7. Each of these changes was made by the legislature after much lobbying by pharmacists, Medicaid officials and others. R.376, A.Ap. 100-01 (circuit court concluding "that a political tug-of-war between various interest groups spanning a number of successive biennial budget sessions resulted in the adoption of reimbursement formulas that were known to overcompensate participating Wisconsin pharmacies").

Particularly in the later years, the debate over where to set the reimbursement level was a subject of great controversy, with Medicaid staff in Wisconsin's Department of Health Services (HHS) arguing for lower reimbursement rates than the legislature was willing to authorize. *See* R.304 (Ex. DX53), A.Ap. 392 (DHS proposal to lower brand drug reimbursement to AWP-15% in the 1999-2001 budget); R.304 (Ex. 292), A.Ap. 404 (same proposal for 2001-03 budget); R.304 (Ex. P1229), A.Ap. 417 (same proposal for 2003-05 budget); R.135 (Ex. 33), Br.Ap. 9-11 (proposal to lower brand drug reimbursement to AWP-16% in the 2005-07 budget).

In 2004, after decades of using AWP with the understanding that it does not refer to actual wholesale prices,

Wisconsin, acting through then-Attorney General Peg Lautenschlauger, filed this lawsuit against 36 drug manufacturers, alleging that AWPs are "untrue, deceptive [and] misleading" under Wis. Stat. § 100.18 and "false" under Wis. Stat. § 49.49.[1] Wisconsin contends that these statutes have been violated because AWP's literal meaning is "average wholesale price," and the numbers published as AWPs do not meet this dictionary definition.

In the course of pursuing this case, Wisconsin has acknowledged that when the legislature established the various "discount from AWP" reimbursement formulae enacted since 1990, it knew that AWP was not an actual average of wholesale prices paid by pharmacists. R.433 (Tr. 57:23-58:8), A.Ap. 306-07 ("[O]f course [Wisconsin] knew [AWPs] were not accurate. That's why they discounted it."). Despite this concession, Wisconsin claims the published AWPs were "untrue," and damaged it. Wisconsin seeks monetary damages, and claims those damages should be measured by calculating the difference between what it

[1] The Non-Pharmacia Brand Defendants, on whose behalf this brief is submitted, are all defendants awaiting trial in this case. Their trials have been stayed pending resolution of this appeal.

reimbursed pharmacists for the ingredient cost of the drugs they dispensed and the wholesale prices that pharmacists paid to acquire those drugs. Wisconsin's damages theory is based on two key premises: first, that the legislature adopted the brand drug reimbursement formulae it did because it was misled by the pharmaceutical industry's use of the term AWP, and second that if the legislature had not been misled it would have chosen a reimbursement formula for brand drugs that provided no margin or profit for pharmacists who agreed to participate in the Medicaid program.

Wisconsin presented this theory to the Pharmacia jury, and that jury returned a verdict based on it. The court of appeals certified, and this Court accepted for review, the question of whether Wisconsin's damage theory requires impermissible speculation in determining damages. The answer to that question is yes. The theory requires a trier of fact to speculate both about why the legislature did what it did, and about what the legislature would have done if it had different information. As numerous decisions of this Court and other courts have established, such speculation about legislative intent – and the speculative reformation of legislation to apply that supposed intent to circumstances

never presented to the legislature – is both dangerous and impermissible. Therefore, the jury's damage award against Pharmacia cannot stand, and Wisconsin's damage theory must be rejected.

ARGUMENT

I. The Jury Had To Impermissibly Speculate In Determining Damages Because It Had To Determine Both Why The Legislature Enacted The Formula It Did And What Formula The Legislature Would Have Enacted If It Had Different Information.

The State did not prove damages with reasonable certainty in this case, because its damages theory required the jury to speculate about the legislature's reasons for making the political and policy judgments it did. The State's damages theory first required the jury to reject the concept that AWP legislation even reflected a policy choice, and to conclude instead that the law was simply an error borne of ignorance that the term "AWP" refers to the benchmark prices published by third party pricing compendia, or ignorance of actual average prices. But, there is no dispute that the legislature was told that AWP is not an actual price, but is more akin to a "sticker price" on a car. R.304 (Ex. DX216), A.Ap. 395. There is also no dispute that, despite

having this knowledge about AWP, the legislature did not seek Wisconsin pharmacists' actual acquisition costs before deciding what the reimbursement rate should be. *See* R.436 (Tr. 68:15-69:7), A.Ap. at 298-99 (Wisconsin requires reports only of pharmacies' usual and customary charges to their customers, not pharmacies' acquisition prices). In these circumstances, the jury could only speculate as to why the legislature set the AWP discount where it did.

The evidence certainly suggests that the legislature made careful policy evaluations. It is undisputed that the legislature was urged by some, particularly the pharmacy lobby, to enact a more generous reimbursement formula to achieve sufficient participation by Wisconsin pharmacists in the Medicaid program. R.304 (Ex. DX216), A.Ap. 396 ("The Pharmacy Society of Wisconsin (PSW) has indicated that reductions to Medicaid pharmacy reimbursement will threaten a pharmacy's ability to service [Medicaid] recipients."); R.304 (Ex. DX543), A.Ap. 424-27 (UW Hospital and Clinics opposing the reduction of reimbursement rates because UW Health pharmacies "cannot engage in contracts where we lose money on services provided" to Medicaid participants). The legislature was also told that to

secure adequate participation, a higher reimbursement rate was needed to offset an inadequate dispensing fee. R.304 (Ex. DX305), A.Ap. 214 ("The Pharmacy Society of Wisconsin argues that pharmacies' margins on the product reimbursement is necessary to cover the costs of dispensing medications to [Medicaid] recipients, since the current [Medicaid] dispensing fee is not sufficient to cover such costs."). Finally, the legislature was told that a higher reimbursement rate was needed to offset higher costs for small, rural pharmacies that were the only source of prescription drugs for some Medicaid patients. R.135 (Ex. 78), Br.Ap. 20 (Senator Dave Hansen stated, "there is a real risk of pharmacies closing, particularly in smaller, more rural communities. I don't want anyone to be denied access to life- or health-saving prescriptions because the state forced their pharmacist out of business.").

But, as Wisconsin concedes in its response brief (p. 25), this evidence of the legislature's knowledge and deliberations is insufficient to establish the legislature's intent. No jury (or court) is allowed to speculate about why the legislature did what it did where the goal is not to construe statutory text but rather to rewrite the law to reflect

circumstances never presented to the legislature. Judicial inquiries into legislative intent uniformly are searches for the intent objectively expressed in statutory text. Even when courts look to extrinsic aids for help, the focus is still on the meaning of the statute's language, not *why* the legislature acted as it did. *State ex rel. Kalal v. Circuit Court*, 2004 WI 58, ¶ 51, 271 Wis. 2d 633, 681 N.W.2d 110. Here, all the legislature did was appropriate an amount of money it was told would enable the Medicaid program to reimburse pharmacists at a specified formula level. R.135 (Ex. 33), Br.Ap. 11 (allocations of general purpose revenue and federal funding to DHS tied to Medicaid reimbursement rate). There is no statutory language explaining why the legislature chose that level, or what it intended to achieve by it.

Moreover, as the Court has long recognized, determining the legislature's subjective intent – *why* the legislature chose to enact a law, as opposed to what it *said* in that law – is not a simple historical fact analogous to the intent of contracting parties. The intent of a legislature cannot be established through the testimony of its members. *See Ball v. District No. 4, Area Board*, 117 Wis. 2d 529, 544, 345 N.W.2d 389 (1984); *Cartwright v. Sharpe*, 40 Wis. 2d

494, 508-09, 162 N.W.2d 5 (1968). Testimony about the legislature's collective "intent" is inherently unreliable. *Juneau County v. Courthouse Employees*, Local 1312, 221 Wis. 2d 630, 644, 585 N.W.2d 587 (1998); *Ball*, 117 Wis. 2d at 545.[2]

Requiring the jury to speculate about whether the legislature enacted the reimbursement formulas it did because it was misled about the meaning of AWP, rather than as a result of a legislative policy decision, is exactly the kind of speculation about subjective intent this Court has renounced. Simply put, no cause of action can be based on the premise that the legislature passed the wrong law. That the jury here was directed to do exactly that is enough, on its own, to invalidate the jury's verdict. Nor does this analysis change if Wisconsin argues that while it understood AWPs were not actual prices, it did not know what the actual prices were. Under this approach, Wisconsin is still asking the jury to speculate about the legislature's intent.

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[2] Of course, information relevant to the legislature (or Medicaid's) *actual knowledge* regarding AWP remains relevant to an assessment of whether AWPs are deceptive, false or misleading under the relevant statutes.

Wisconsin's damage theory not only required the jury to determine why the legislature did what it did, it also required the jury to do something even more difficult and radical: to determine what action the legislature *would have taken* if it had more or different information about the nature of the AWPs published in the pricing compendia or, as Wisconsin may contend, if published AWPs were actual average prices rather than reference prices. In essence, Wisconsin's damage theory put the jury through an exercise in what has been called "imaginative reconstruction," asking the jury to determine "what . . . the legislature would have done (had it faced the question explicitly) rather than what the legislature actually did." *United States v. Logan*, 453 F.3d 804, 807 (7th Cir. 2006). As a method of statutory interpretation, imaginative reconstruction has been discredited as democratically illegitimate, "for it sets up the judiciary as the effective lawmakers." *Id.* (citing *West Virginia University Hospitals, Inc. v. Casey*, 499 U.S. 83, 100-01 (1991) and *Tafflin v. Levitt*, 493 U.S. 455, 461-62 (1990)). It fares no better as a means of determining an award of damages. Juries are in no better a position than courts to decide what the legislature would have done, or

should have done, if different information had been available to it.

Even assuming that a non-speculative basis could exist to support a jury's determination about hypothetical legislative action, there surely is no such basis for determining in this case what the legislature would have done if it had even more information that the AWPs published by the pricing compendia were not actual average prices. Would the legislature have insisted, contrary to the actual record, that it be given actual prices by pharmacists and then set the reimbursement level at those prices with no margin? Would it have insisted on getting those actual prices but then set the reimbursement level at something other than those prices to account for the concerns raised by pharmacists? Or would it have set overall reimbursement at exactly the same level it did? Under Wisconsin law, no jury is authorized to make such a purely speculative determination.

II. Wisconsin's Attempt To Save Its Damages Award By Claiming That DHS, Not The Legislature, Set The Reimbursement Rate, And That Federal Law Required Reimbursement At Actual Cost, Fails.

Perhaps sensing the danger posed by its speculative damages theory, Wisconsin argues that the jury did not have

to speculate about legislative intent because (1) DHS, not the legislature, determined the reimbursement rate, and (2) in any event, the legislature had no alternative under federal law but to reimburse at actual cost, and it must be assumed the legislature followed the law. The first argument is factually incorrect; the second argument misstates the law.

For brand drugs, it is simply not true that DHS made the final call on reimbursement rates. The record demonstrates that in four consecutive budget cycles, DHS proposed reimbursement reductions that were never adopted by the legislature and thus never put in place. *See* R.304 (Ex. DX53), A.Ap.392); R.304 (Ex. 292), A.Ap.404; R.304 (Ex. P1229), A.Ap.417; R.135 (Ex. 33), Br.Ap. 9-11. As the circuit court found, Medicaid reimbursement has been a hard-fought political question involving "both the legislative and executive branches." R.376 (A.Ap. 101).

Nor does federal law require the State to reimburse pharmacists at their actual costs of acquisition with no allowance of profit. The regulations require that reimbursement for brand-name drugs may "not exceed, *in the aggregate* . . . [providers' estimated acquisition costs ("EAC")] *plus* reasonable dispensing fees . . . ." 42 C.F.R. §

447.512(b) (emphasis added). As the State acknowledges, the second component of this aggregate – the dispensing fee – reimburses "for the professional services provided by the pharmacist when dispensing a prescription (including overhead expenses *and profit*)." State's Resp. Br. at 6 (emphasis added) (quoting a 2011 report by the HHS Office of Inspector General). A state can reimburse in a manner that provides this profit to pharmacists *either* through the formula for estimated acquisition costs *or* through the dispensing fee, because § 447.512(b) caps reimbursement for acquisition costs and dispensing fees only "in the aggregate." As the Department of Health and Human Services Departmental Appeals Board (DAB) – HHS's final authority on whether agency action with respect to Medicaid reimbursement is lawful – has ruled, states can "offset a lower than reasonable dispensing fee with ingredient costs which were higher than . . . the costs to the pharmacies . . . ." Pa. Dep't of Public Welfare, D.A.B. No. 1315 (1992), Br.Ap. 40; *see also Arizona Health Care Cost Containment System v. McClellan*, 508 F.3d 1243, 1249, 1254 (9th Cir. 2007) (deferring to DAB's interpretation of a Medicaid statute).

Recent experience in Alabama demonstrates how states analyze acquisition costs and dispensing fees as part of an aggregate whole. In 2010, Alabama switched from a reimbursement system based on a discount off AWP to a new reimbursement system based on a drug's surveyed actual acquisition cost. Alabama Medicaid Agency, *CMS approves AAC drug pricing method, dispensing fee increase*, http://medicaid.alabama.gov/news_detail.aspx?ID=3898 (last visited Sep. 27, 2011), Br.Ap. 24-25. At the same time, however, Alabama Medicaid submitted – and the Centers for Medicare and Medicaid Services (CMS) approved – a companion request to nearly double the Medicaid dispensing fee, from $5.40 to $10.64 per prescription. *Id.* This illustrates Alabama and CMS's recognition that Alabama's previous inadequate dispensing fee had been cross-subsidized by its AWP-based drug reimbursement. Wisconsin's dispensing fee for brand drugs is currently $3.44 – just 32% of the dispensing fee newly adopted by Alabama to offset its shift to a reimbursement formula based on actual acquisition costs. CMS, *Medicaid Prescription Reimbursement Information by State – Quarter Ending March 2011*, https://www.cms.gov/reimbursement/Downloads%5C1Q2011

ReimbursementChart.pdf (last visited Sep. 27, 2011), Br.Ap. 26-32.

The State's characterization of federal law is also belied by CMS's approval of numerous state plans that clearly reimburse for ingredient costs above actual acquisition prices. Even though Wisconsin has asserted since 2004, when it initiated this action, that its AWP-based reimbursement formula overcompensates pharmacists, CMS to this day accepts not only Wisconsin's state Medicaid plan but also other state plans featuring *higher* reimbursement rates. *See id.* (CMS approved brand-drug reimbursement rates of AWP-10% in the District of Columbia and South Carolina; AWP-10.25% in Virginia; AWP-11% in Georgia, Nebraska, and Wyoming; and AWP-12% in Idaho, Illinois, Iowa, and Minnesota).

CONCLUSION

This Court should reverse the judgment of the circuit court and order that the jury verdict be vacated.

Dated this 6th day of October, 2011.

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Submitted on Behalf of all Non-Pharmacia Brand Defendants

CERTIFICATION OF FORM AND LENGTH

I hereby certify that this brief conforms to the rules contained in s. 809.19(8)(b) and (c) for a brief and appendix produced with a proportional serif font. The length of this brief is 2,984 words.

Dated this 6th day of October, 2011

/s/ *Matthew J. Splitek*

CERTIFICATE OF COMPLIANCE WITH RULE 809.19(12)

I hereby certify that I have submitted an electronic copy of this brief which complies with the requirements of s. 809.19(12). I further certify that the electronic brief is identical in content and format to the printed form of the brief filed as of this date.

Dated this 6th day of October, 2011

/s/ *Matthew J. Splitek*

CERTIFICATE OF SERVICE

I hereby certify that on this day, I caused three true and correct copies of this brief and appendix to be served by first-class mail, postage prepaid, upon the persons listed below:

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